

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

I. Claim Amendments

Claims 12, 14, 22, 29-30, 32 and 33 were pending in this application when the RCE was filed on May 26, 2011.

The preambles of claims 12 and 14 have been amended to delete the intended use language of “for medicines, animal drugs, agricultural chemicals, fertilizers or foods”, and to recite “An aqueous coating solution”. Similarly, the preamble of claim 33 has been amended to recite “An aqueous binder solution”. Support for these amendments can be found on page 3, line 26 and page 15, line 7 of the clean version of the substitute specification.

Claims 12, 14 and 33 have also been amended to recite “the partially hydrolyzed polyvinyl alcohol excludes a thiol-modified polyvinyl alcohol”. Support for this amendment can be found on page 12, line 26 to page 13, line 2 of the clean version of the substitute specification.

Claims 12, 14 and 33 have also been amended to make minor editorial changes in view of the above-discussed amendments.

Claims 22, 29, 30 and 32 have been amended to correspond with the amendments to claims 12 and 14.

New claims 34-39 have been added to correspond with claims 12, 30, 32, 14, 22 and 29, respectively, but which are directed to an “aqueous coating suspension”. New claim 40 has been added to correspond with claim 33, but which is directed to an “aqueous binder suspension”.

New claims 41-46 have been added to correspond with claims 12, 30, 32, 14, 22 and 29, respectively, but which are directed to an “organic solvent coating solution”. New claim 47 has been added to correspond with claim 33, but which is directed to an “organic solvent binder solution”.

New claims 48-53 have been added to correspond with claims 12, 30, 32, 24, 22 and 29, respectively, but which are directed to an “organic solvent coating dispersion”. New claim 54 has been added to correspond with claim 33, but which is directed to an “organic solvent binder dispersion”.

Support for the new claims can be found on page 15, lines 2-8 of the clean version of the substitute specification, and Example 7.

II. Personal Interview

Applicants appreciate the courtesies extended to Applicants' attorney by Examiner Buie-Hatcher and Examiner Eashoo during the personal interview held June 13, 2011.

During the interview, first the amendments filed May 26, 2011 were discussed. The Examiners indicated that the feature "coating composition for medicines, animal drugs, agricultural chemicals, fertilizers or foods", and the term "binder" are considered intended use limitations, which are not given any patentable weight under U.S. practice. As a result, the Examiners did not find these features to distinguish over the "hard capsule" disclosed by Hoshi et al. (WO 02/17848; U.S. 2003/01667163).

Next, Applicants' attorney asserted that Hoshi et al. do not disclose any synthetic examples of "a copolymer consisting of a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500 and a polymerizable vinyl monomer in a weight ratio of 6:4 to 9:1, wherein the polymerizable vinyl monomer consists of acrylic acid and methyl methacrylate combined in a weight ratio of 3:7 to 0.5:9.5 in the copolymer", as recited in claims 12, 14 and 33. The Examiners indicated that PVA-SH, as used in Synthesis Examples 1-3 of the reference, is equivalent to "a partially hydrolyzed polyvinyl alcohol", because the claims do not exclude a "modified version" of a polyvinyl alcohol.

Applicants' attorney also argued that the mixing proportions of the PVA-SH of the references' examples create an average polymerization degree outside of "300 to 500".

Next, Applicants' attorney asserted that claims 12, 14 and 33 recite the polymerizable vinyl monomer consists of "acrylic acid" and methyl methacrylate, and the reference teaches a polymerizable vinyl monomer of "methacrylic acid" and methyl methacrylate.

Examiner Buie-Hatcher indicated that Applicants could file supplemental amendments prior to issuing another Office Action. Applicants greatly appreciate the Examiner's willingness to permit Applicants to file supplemental amendments.

Applicants have carefully considered the Examiners' comments, and have amended the claims and provide the following remarks in view of these comments.

III. Claim Rejections Under 35 U.S.C. § 102

Claims 12, 30 and 31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hoshi et al., and claims 14, 22 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshi et al. As applied to the amended claims, Applicants respectfully traverse the rejections.

“A claim is anticipated **only if each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (see MPEP 2131).

Hoshi et al. teach a “**hard capsule**” that is mainly made of a polymer or copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of a polyvinylalcohol and/or a derivative thereof (see paragraphs [0001], [0004] and [0060]-[0090]).

Under MPEP 2111.02, the determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case, and there is no litmus test defining when a preamble limits the scope of a claim. However, “**Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation**” (see MPEP 2111.02, emphasis added, citing *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)).

Furthermore, according to MPEP 2111.02, during examination, “statements in the preamble reciting the purpose or intended use of the claimed invention **must be evaluated to determine whether the recited purpose or intended use results in a structural difference** (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. **If so, the recitation serves to limit the claim**” (see *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (emphasis added)).

Claims 12 and 14 have been amended to recite the preamble “An aqueous coating solution”. A person having ordinary skill in the art would recognize that an “aqueous coating solution” is a **liquid**, which clearly has different structural features from a “**hard capsule**”. A (liquid) aqueous coating solution is clearly structurally distinct from a hard capsule. Therefore, the aqueous coating solution of claims 12 and 14 are clearly distinguished from the “hard capsule” of Hoshi et al.

In addition, claims 12 and 14 recite “a copolymer **consisting of** a hydrolyzed polyvinyl alcohol having **an average polymerization degree of 300 to 500**”; “the polymerizable vinyl monomer **consists of acrylic acid and methyl methacrylate** combined in a weight ratio of 3:7

to 0.5:9.5 in the copolymer”; and “the partially hydrolyzed polyvinyl alcohol **excludes a thiol-modified polyvinyl alcohol**”.

Hoshi et al. fail to disclose a copolymer having each and every feature of the copolymer of claims 12 and 14.

Synthesis Example 1 of Hoshi et al. includes PVA-SH, methacrylic acid and methacrylate. However, claims 12 and 14 recite “the polymerizable vinyl monomer **consists of acrylic acid and methyl methacrylate**”; and “the partially hydrolyzed polyvinyl alcohol **excludes a thiol-modified polyvinyl alcohol**”. Therefore, claims 12 and 14 exclude PVA-SH, as is present in the reference’s example, and the copolymer in the reference’s example has methacrylic acid and methacrylate, rather than acrylic acid and methyl methacrylate, as required in the copolymer of claims 12 and 14. Accordingly, Synthesis Example 1 does not anticipate claims 12 and 14.

Synthesis Example 2 of Hoshi et al. discloses a copolymer comprising (1) a **mixture of PVA-SH** having a polymerization degree of **500 and 1500** (a mixture of 50:50, 45:55, 40:60, 20:80 or 10:90 of 500 and 1500), and (2) acrylic acid and methyl methacrylate (see paragraph [0055] and Table 2). This example is distinguished from claims 12 and 14, because it includes PVA-SH, and claims 12 and 14 recite “the partially hydrolyzed polyvinyl alcohol **excludes a thiol-modified polyvinyl alcohol**”. In addition, this example does not have “**an average polymerization degree of 300 to 500**”, as recited in claims 12 and 14. Therefore, Synthesis Example 2 does not anticipate claims 12 and 14.

Synthesis Example 3 of the reference includes PVA-SH, methacrylic acid and methyl methacrylate. This example is distinguished from claims 12 and 14, because it includes PVA-SH, and claims 12 and 14 recite “the partially hydrolyzed polyvinyl alcohol **excludes a thiol-modified polyvinyl alcohol**”. In addition, the copolymer in this example has methacrylic acid and methacrylate, rather than “acrylic acid and methyl methacrylate”, as required in claims 12 and 14. Therefore, Synthesis Example 3 does not anticipate claims 12 and 14.

Synthesis Example 4 of the reference discloses a copolymer comprising (1) a **mixture of PVA** having a polymerization degree of **500 and 1700** (a mixture of 50:50, 45:55, 40:60, 20:80 or 10:90 of 500 and 1700), and (2) acrylic acid and methyl methacrylate (see paragraph [0059] and Table 4). This example does not have “a copolymer **consisting of** a hydrolyzed polyvinyl alcohol having **an average polymerization degree of 300 to 500**”, because it teaches a mixture

of a PVA having a polymerization degree of **500 and 1700**, which cannot create an average of “300 to 500” with mixture ratios of 50:50, 45:55, 40:60, 20:80 or 10:90. Therefore, Synthesis Example 4 does not anticipate claims 12 and 14.

Furthermore, claims 12 and 14 recite “a copolymer **consisting of** a hydrolyzed polyvinyl alcohol having **an average polymerization degree of 300 to 500**”. When a copolymer consisting of a hydrolyzed polyvinyl alcohol has an average polymerization degree **outside of 300 to 500**, then the PVA copolymer shows considerable spinnability (thread-forming properties), and it cannot be used for coating purposes. Thus, it is unsuitable for use in an “aqueous coating solution”.

In addition, the following table, which was filed on February 11, 2011, shows the differences of physical properties between two copolymers (the Present Invention and the Control) consisting of:

Present Invention: ① polyvinyl alcohol (PVA) (mixture ratio = 1 (polymerization degree: 500): 9 (polymerization degree: 1500)); ② acrylic acid; and ③ methyl methacrylate (MMA).

Control: ① PVA; ④ methacrylic acid (MAA) and ③ MMA.

Table

	Present invention	Control
①PVA/②acrylic acid	75/25	-
①PVA/④MAA	-	75/25
polymerization degree of PVA: 500	10/90	10/90
polymerization degree of PVA: 1500		
③MMA/②acrylic acid	70/30	-
③MMA/④MAA	-	70/30
Viscosity mPa · s/25°C	20100	91600
Water solubility	within 10 min.	over 10 min.

PVA: polyvinyl alcohol

MAA: methacrylic acid

MMA: methyl methacrylate

As shown in the Table, the viscosity of the control copolymer, which consists of PVA, **MAA (methacrylic acid)** and MMA (methyl methacrylate) (corresponding to Hoshi et al.), is much higher than that of the copolymer of claims 12 and 14, which consists of PVA, **acrylic acid** and MMA. Furthermore, as shown in the Table, the water solubility of the control

copolymer is much lower than that of the copolymer of claims 12 and 14. As a result, the control copolymer is unsuitable for use in “an aqueous coating solution”. Therefore, the resulting control copolymer is completely different in physical properties and structural features from the copolymer of claims 12 and 14.

In view of the foregoing, one skilled in the art would recognize that the reference fails to disclose an aqueous coating solution comprising a copolymer, as defined in claims 12 and 14. Therefore, claims 12 and 14 are not anticipated by the reference.

Claims 22 and 30 depend from claim 12 or 14, and thus also are not anticipated by the reference. Claims 28 and 31 have been cancelled.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

IV. Claim Rejections Under 35 U.S.C. § 103

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 4,341,563) in view of Hoshi et al.; claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. in view of Hoshi et al.; and claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zeidler et al. (US 6,001,391) in view of Hoshi et al. As applied to the amended claims, Applicants respectfully traverse the rejections.

Kurihara et al. and Hoshi et al.

As the Examiner indicates, Kurihara et al. describe a coating solution used to form a film comprising a water-soluble film base, such as polyvinyl alcohol, and a coated solid medicine (see Office Action of August 13, 2010, page 5, lines 15-17). The Examiner acknowledges that the reference does not disclose the copolymer recited in claims 12 and 14, but asserts that Hoshi et al. remedy this deficiency (see Office Action, page 5, lines 18-22 and page 6, lines 5-9).

However, for the reasons discussed above, the hard capsule of Hoshi et al. is structurally distinct from the aqueous coating solution of claims 12 and 14. Therefore, claims 12 and 14 would not have been obvious over Kurihara et al. and Hoshi et al.

Claims 29 and 32 depend from claims 14 and 12, respectively, and thus also would not have been obvious over the references.

Zeidler et al. and Hoshi et al.

As the Examiner indicates, Zeidler et al. describe that polyvinyl alcohol or copolymers of MMA and acrylic acid are used as a binder (see Office Action, page 7, lines 9-11). The Examiner acknowledges that the reference does not disclose the copolymer of claims 12 and 14,

but asserts that Hoshi et al. remedy this deficiency (see Office Action, page 7, line 12 – page 8, line 5).

Hoshi et al. fail to disclose an aqueous coating solution comprising a copolymer, as defined in claims 12 and 14. Claim 33 is directed to an aqueous “binder” solution comprising a copolymer having the same features as recited in claim 14. A person having ordinary skill in the art would recognize that an “aqueous binder solution” is a liquid, which clearly has different structural features from a “hard capsule”. Therefore, the aqueous binder solution of claim 33 is clearly distinguished from the “hard capsule” of Hoshi et al.

Therefore, claim 33 would not have been obvious over Zeidler et al. and Hoshi et al.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

V. New Claims

Claims 34, 35, 37 and 38 are directed to aqueous coating suspensions, and claim 40 is directed to an aqueous binder suspension.

Claims 41, 42, 44 and 45 are directed to organic solvent coating solutions, and claim 47 is directed to an organic solvent binder solution.

Claims 48, 49, 51 and 52 are directed to organic solvent coating dispersions, and claim 54 is directed to an organic solvent binder dispersion.

For the reasons discussed above, a person of ordinary skill in the art would recognize that each of these claims is directed to a liquid, and are thus distinguished from the “hard capsule” of Hoshi et al. In addition, these liquids comprise a copolymer that is clearly distinguished from the reference for the reasons discussed above.

Claims 36, 39, 43, 46, 50 and 53 depend from claim 34, 37, 41, 44 or 48, and thus also are distinguished over the references.

Accordingly, prompt examination and allowance of these claims are respectfully requested.

VI. Conclusion

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejections set forth by the Examiner have been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Makoto NOAMI et al.

By /Andrew B. Freistein/


Digitally signed by /Andrew B. Freistein/
DN: cn=/Andrew B. Freistein/, o=WLP,
ou=WLP, email=a.freistein@wenderoth.
.com, c=US
Date: 2011.09.08 13:06:55 -04'00'

Andrew B. Freistein
Registration No. 52,917
Attorney for Applicants

ABF/emj
Washington, D.C. 20005-1503
Telephone (202) 721-8200
Facsimile (202) 721-8250
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